DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M3175n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

AUG 1 2 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeffrey Roberto, President
Sushi On A Roll, Inc.
7595 Vickers Street
San Diego, California 92111

W/L 38-9

Dear Mr. Roberto:

On April 14 & 15, 1999, an Investigator from the Food and Drug Administration (FDA) conducted an inspection of your firm, located at 7595 Vickers Street, San Diego, California. At the conclusion of the inspection you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation); and 21 CFR Part 110 – Good Manufacturing Practices (GMP) for Foods. A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act).

Specifically, we found the following deficiencies related to the following ready-to-eat seafood products, which are air-packaged and stored and sold as refrigerated items. These finished products include:

- Tuna Rolls (raw tuna, etc. wrapped in seaweed and rice)
- Smoked Salmon Rolls (smoked salmon etc. wrapped in seaweed and rice)
- California Rolls (imitation crab meat, etc. wrapped in seaweed and rice)
- Tuna Sushi (raw tuna placed on rice)
- Hamachi Sushi (raw yellowtail placed on rice)

1. Failure to have and implement a HACCP plan for the sushi products listed above to control one or more hazards that are reasonably likely to occur [21 CFR 123.6(b)]. For example, rice used in the manufacture of these products is held at ambient temperatures for up to 24 hours thereby allowing for conditions which

could result in the our growth of pathogens including *Bacillus cereus* [21 CFR 123.6(c)(1)]. In addition, the hazard of scombrotoxin (histamine) formation in raw tuna and yellowtail, which is used in a number of the sushi products listed above, is reasonably likely to occur in the absence of time temperature controls.

2. Your firm is not monitoring sanitation conditions and practices in your processing facility as required in 21 CFR 123.11 (b), and recording the results of those monitoring activities per 21 CFR 123.11 (c). This monitoring must cover, at a minimum, each of the eight key sanitation conditions and practices described in 21 CFR Part 123.11 which apply to your facility and operations. As ready-to-eat items, that is products that are eaten directly by consumers without cooking, sanitation controls are also especially important to ensure the safety of those items.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please note that we find the aforementioned conditions particularly significant in light of prior notification of HACCP deficiencies communicated by FDA to your firm. These deficiencies were first noted at the close of an inspection of your firm on September 28, 1998, and then secondly via an untitled letter sent to you dated November 16, 1998. Both the Form FDA-483 left with your firm during the September, 1998 inspection and the letter cited HACCP deficiencies (i.e. lack of a HACCP plan and sanitation monitoring) in your firm. Furthermore, your firms' Vice President, Michael S. Reyes promised immediate corrections during the closeout discussion from the September, 1998 inspection.

We note that during the closeout discussion with FDA on 4/15/99, one of the reasons your firm has not developed HACCP plans, etc. when needed, was that you and /or your staff has not had the time to take a HACCP training course. We do not consider this comment a justifiable reason to defer implementing required Federal HACCP regulations. There are multiple options at your firm's disposal to fulfill the requirements of the 21 CFR 123. These options include hiring a competent consultant to develop and implement your HACCP plan(s), self-study, or a combination of these two options. If you have internet access, then please visit the HACCP information on FDA's website at www.fda.gov.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include a copy of HACCP plans developed, SSOP (if applicable) and sanitation monitoring forms or procedures. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be directed to:

Thomas L. Sawyer, Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

Sincerely,

James L Kozich

Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief